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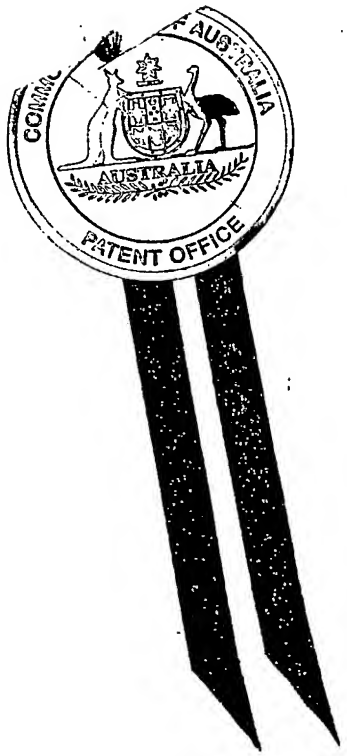
I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2004900363 for a patent by UNITRACT SYRINGE PTY LTD as filed on 28 January 2004.



WITNESS my hand this
Ninth day of February 2005

JANENE PEISKER
TEAM LEADER EXAMINATION
SUPPORT AND SALES

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Regulation 3.2

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: "AUTO-DISABLE SYRINGE"

The invention is described in the following statement:

TITLE

AUTO-DISABLE SYRINGE

FIELD OF THE INVENTION

THIS INVENTION relates to syringes. More particularly, this invention relates a syringe that includes a mechanism to prevent re-use of the syringe.

BACKGROUND OF THE INVENTION

The practice of sharing syringes without adequate sterilisation between successive users is a major contributor to the transfer of Human Immunodeficiency Virus (HIV) and Hepatitis with subsequent severe repercussions for the sufferer and at a high cost to society for supporting and providing medical attention to sufferers.

In response to this problem, syringes have been developed with the aim of preventing syringe re-use.

One solution has been to develop syringes where the needle is permanently retractable into the barrel of the syringe, retraction driven by a compressed spring, as for example described in International Publication WO 01/80930.

Although very effective, retractable syringes are relatively expensive, particularly when required in large quantities for mass immunizations or for distribution to intravenous drug users. This is particularly a problem in third world countries where the incidence of HIV is high, mass immunization programs need to be frequently undertaken and healthcare resources are limited.

Several simpler and less expensive non-retractable syringe alternatives exist, such as syringes having disabling mechanisms that prevent re-use, but generally these syringes require the user to actively disable the syringe. Even health care

professionals can at times be remiss and fail to actively disable such syringes after use.

SUMMARY OF THE INVENTION

The present invention is therefore broadly directed to a syringe which comprises a mechanism to automatically disable the syringe and thereby prevent re-use of the syringe, which syringe is relatively simple and inexpensive to manufacture.

In a first aspect, the invention provides a plunger for a syringe that comprises a collar having at least one pawl for engaging said plunger, said plunger comprising at least one longitudinal ratchet engageable with said at least one pawl, in use operable to prevent withdrawal of said plunger during depression of said plunger.

In a second aspect, the invention provides a syringe comprising a plunger, a barrel and a collar having at least one pawl, said plunger comprising at least one longitudinal ratchet engageable with said at least one pawl, which in use operable to prevent withdrawal of said plunger during depression of said plunger.

In a third aspect, the invention provides a disabling system for a syringe, said system comprising a plunger having at least one ratchet and a collar mountable to a barrel of said syringe, said collar comprising an inner collar and an outer collar having at least one pawl engageable with said ratchet, said inner collar operable to prevent engagement of said ratchet by said at least one pawl until said plunger is depressed.

In a fourth aspect, the invention provides a method of operating a syringe having a plunger and a collar comprising at least one pawl engageable with said plunger, said method including the step of depressing said plunger from a first

position at which said at least one pawl is not engageable with said plunger to a second position at which said at least one pawl is engageable with said plunger and thereby prevents withdrawal of said plunger.

In a preferred embodiment, said plunger comprises two opposed ratchets, each disposed longitudinally along said plunger.

According to this embodiment, said collar comprises two pawls, each said pawl engageable with a respective said opposed ratchet to prevent withdrawal of said plunger during or following depression of said plunger.

The longitudinal ratchet may comprise a plurality of aligned steps, teeth, abutments or ridges oriented relative to said one or more pawls so as to be capable of engaging said one or more pawls, in use to prevent withdrawal of said plunger during or following depression of said plunger.

Throughout this specification, unless otherwise indicated, "comprise", "comprises" and "comprising" are used inclusively rather than exclusively, so that a stated integer or group of integers may include one or more other non-stated integers or groups of integers.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting embodiments of the invention are described herein with reference to drawings wherein:

FIG. 1 is a perspective view of a longitudinal section through an embodiment of a syringe;

FIG. 2 is a perspective view of an embodiment of a plunger;

FIG. 3 is a perspective view of an embodiment of an outer collar;

FIG. 4 is a perspective view of an embodiment of an inner collar;

FIG. 5 is a plan view of a longitudinal section through an embodiment of a syringe during plunger withdrawal; and

FIG. 6 is a plan view of a longitudinal section through an embodiment of a syringe during plunger depression.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, syringe 10 comprises barrel 11 and plunger 20. Barrel 11 comprises needle end 13 to which is mountable a needle (not shown). Barrel 11 also comprises flared end 14 at which are located paired finger grips 15 and locating slots 16 in which is mounted barrel-engaging shoulders 45A, 45B of outer collar 40. Inner collar 50 is shown initially engaged with outer collar 40. Barrel 11 may be of any capacity, although preferably barrel 11 is suitable for a syringe of less than 1.0 mL capacity, for example a 0.5 mL syringe.

Plunger 20 can be seen in more detail in FIG. 2. Plunger 20 comprises rod 21 with button 22 operable by a user, and opposed ratchets 23, each disposed longitudinally along plunger rod 21. Ratchets 23 each comprise a plurality of steps 24 which each have deep shoulder 26 and shallow shoulder 27. There is also an inclined surface 25 intermediate adjacent steps 24.

Plunger rod 21 further comprises opposed guide slots 28, each of which comprises ramped abutment 29 each comprising ramp 30 and ledge 33. Guide slots assist maintaining a correct orientation of plunger 28 in use, while ledges 33 prevent complete withdrawal of plunger 20 from barrel 11, as will be described in more detail hereinafter. Ramps 30 assist in assembling plunger 20 into barrel 11.

Needle end 31 of plunger 20 comprises nub 32 which fits into seal 60, as can be more readily seen in FIG. 1.

Referring now to FIG 3, outer collar 40 comprises outer collar body 41 having pawls 42A, 42B, channels 43A, 43B, fingers 44A, 44B and barrel-engaging shoulders 45A, 45B. Pawls 42A, 42B are resiliently deformable from an initial position where engagement with steps 24 is prevented to a position where pawls 42A, 42B can engage steps 24 to prevent plunger withdrawal, as will be described in more detail hereinafter.

As can be seen in FIG 4, inner collar 50 comprises inner collar body 51 having first projection 52A and second projection 52B, which projections are resiliently deformable in the direction indicated by arrows. Inner collar body 51 also comprises tabs 54A, 54B.

With this in mind and with reference to FIG. 5, when assembled, barrel-engaging shoulders 45A, 45B of outer collar 40 fit into respective locating slots 16 of flared plunger end 14 of barrel 11 of syringe 10. Tabs 54A, 54B of inner collar 50 are slidably located in channels 43A, 43B of outer collar 40 (not shown). This aligns inner collar 50 and outer collar 40, preventing rotation therebetween. Alignment and non-rotation of plunger 20 is facilitated by fingers 44A, 44B of outer collar 40 slidably engaging respective, opposed guide slots 28 on plunger rod 21 (not shown).

In this correctly aligned and non-rotatable configuration, first projection 52A and second projection 52B of inner collar 50 are initially, respectively positioned between pawls 42A, 42B of outer collar 40 and ratchets 23A, 23B, thereby preventing pawls 42A, 42B of collar 40 contacting steps 24A, 24B.

It can be seen that during withdrawal of plunger 20 to fill barrel 11, pawls 42A, 42B tend to exert an inward pressure on projections 52A, 52B thereby clamping projections 52A, 52B in position. Accordingly, projections 52A, 52B pass over respective steps 24A, 24B with minimal interference thereby providing a "smooth" feel during plunger 20 withdrawal.

Referring to FIG. 2 and FIG. 5, fingers 44A, 44B of outer collar 40 slidably that engage respective, opposed guide slots 28 on plunger rod 21, in use bear against ledges 33 if plunger 20 is withdrawn beyond a certain point to thereby prevent further plunger withdrawal. This prevents complete withdrawal of plunger 20 from barrel 11.

Referring to FIG. 5 and FIG. 6, upon depression of plunger 20, projections 52A, 52B of inner collar respectively engage shallow shoulders 27A, 27B of steps 24A, 24B at whichever point has been reached during withdrawal of plunger 20. The force applied to plunger 20 by the user pushes shallow shoulders 27A, 27B of steps 24A, 24B against projections 52A, 52B respectively, thereby forcing inner collar 50 out of its initial position engaged with outer collar 40 to thereby expose pawls 52A, 52B. It can be seen in FIG. 6 that projections 52A, 52B return to a non-deformed position and no longer contact ratchets 24A, 24B.

Referring again to FIG. 6, due to the respective orientations of pawls 42A, 42B of outer collar 40, the direction of inclined surfaces 25A, 25B and the relative shallowness of shallow shoulders 27A, 27B, pawls 42A, 42B do not appreciably interfere with depression of plunger 20 which provides a "smooth" feel to the user during delivery. However, should the user attempt to subsequently withdraw plunger 20 to re-fill syringe 10, pawls 42A, 42B respectively engage deep shoulders 26A,

26B of steps 24A, 24B in ratchets 23A, 23B to thereby prevent withdrawal of plunger 20 and re-use of syringe 10.

In light of the foregoing it will be appreciated that the present invention provides a relatively simple, robust and inexpensive syringe that is automatically disabled with little or no assistance from the user to thereby prevent, or at least minimize the likelihood of, re-use of the syringe.

Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Various changes and modifications may be made to the embodiments described and illustrated without departing from the present invention. In particular, opposed ratchets 23A, 23B need not be located at 180° with respect to each other, but may readily adopt different, relative positions on plunger 20 while performing the same function. Furthermore, the number of ratchets 23 and steps, teeth, ridges or abutments 24 that form the ratchet may be readily modified, as may be the number of pawls 42 on collar 40.

DATED this twenty-eighth day of January 2004

UNITRACT SYRINGE PTY LTD

by its Patent Attorneys

FISHER ADAMS KELLY

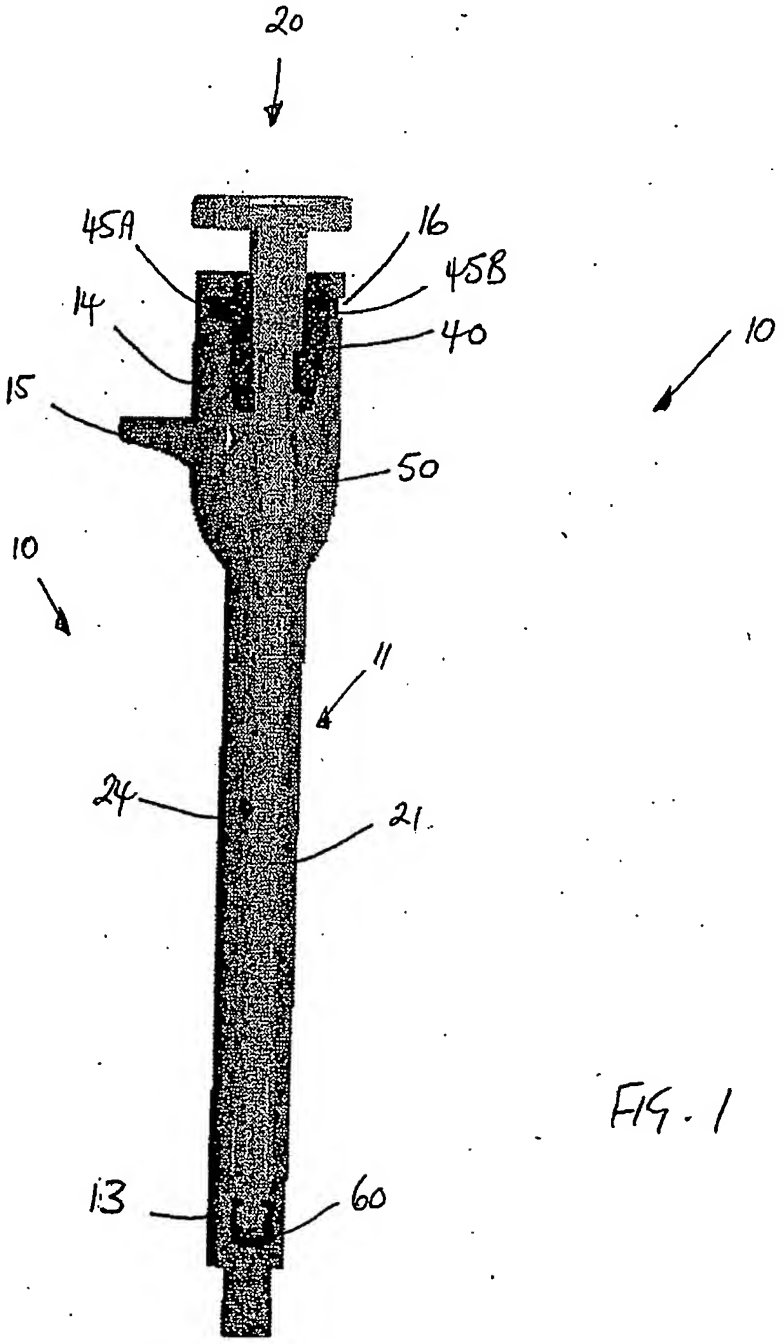


FIG. 1

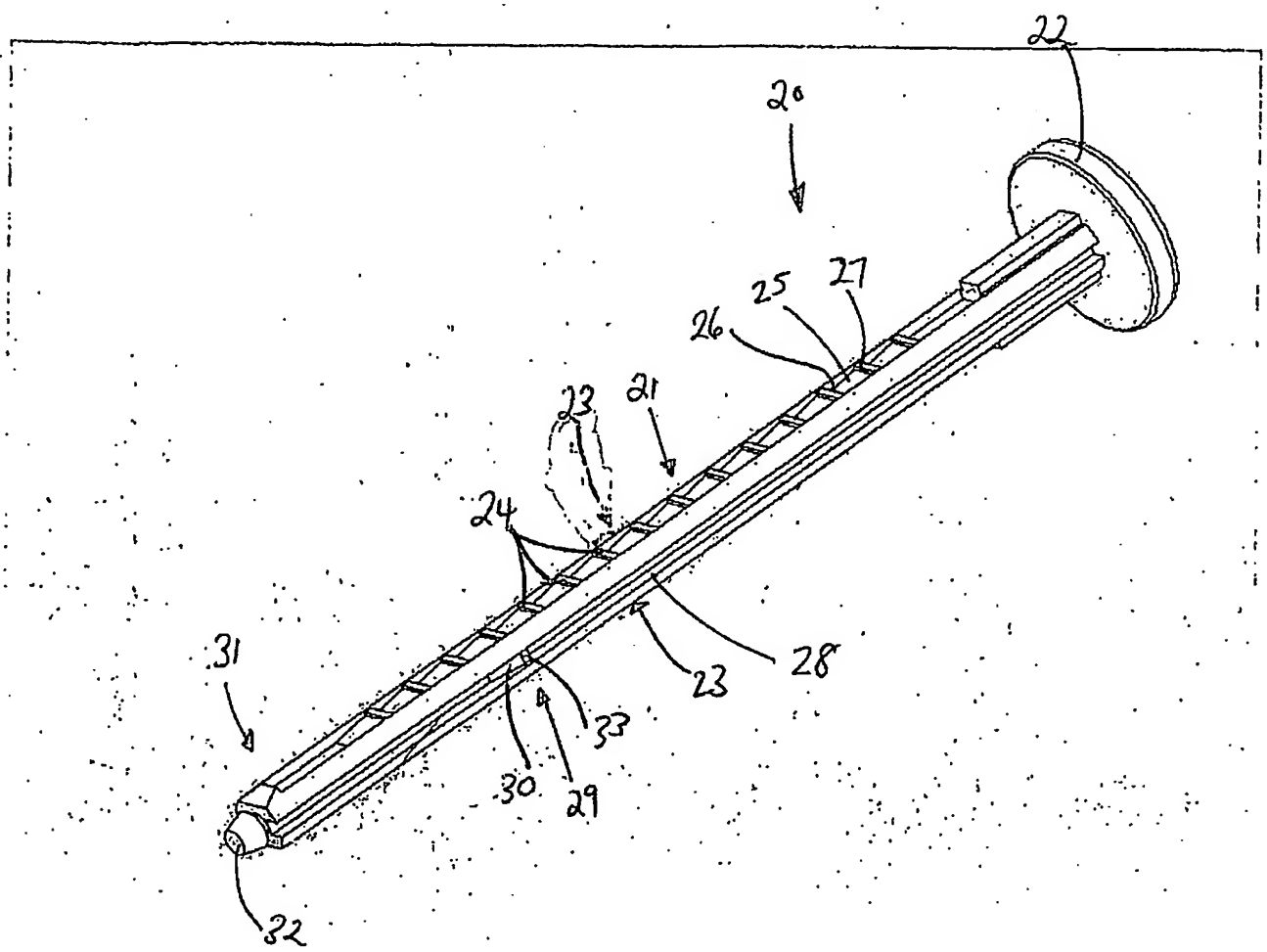


FIG. 2

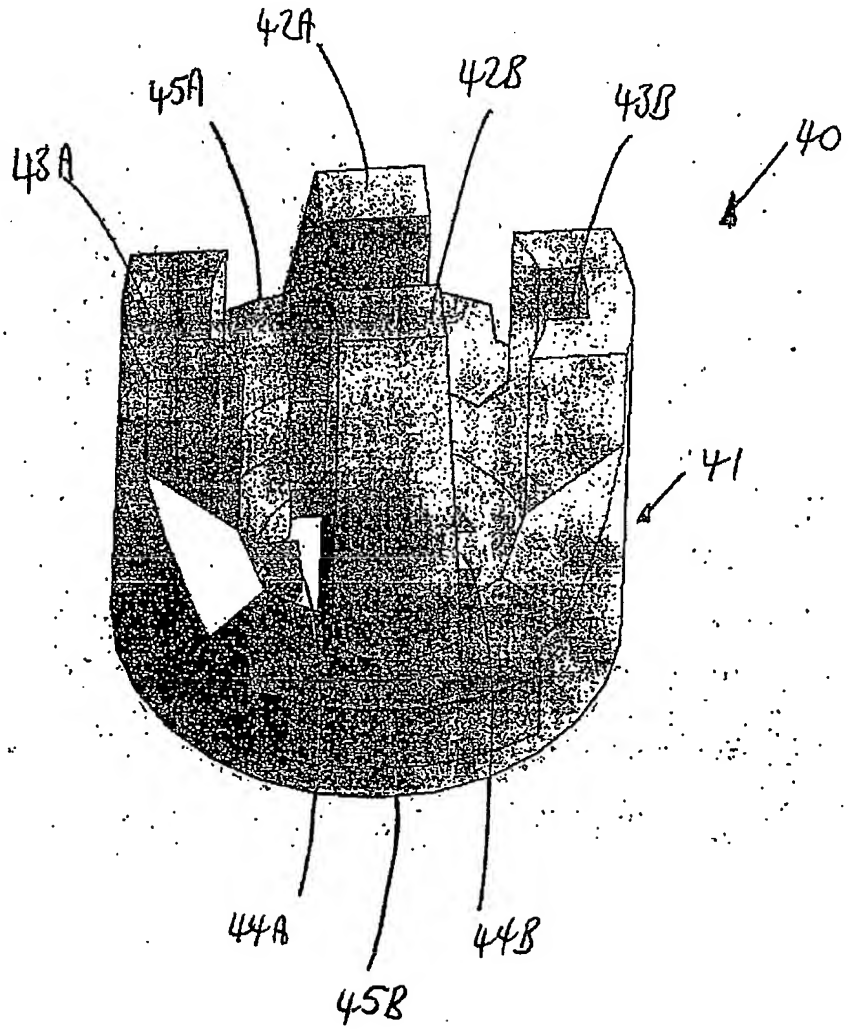


FIG. 3

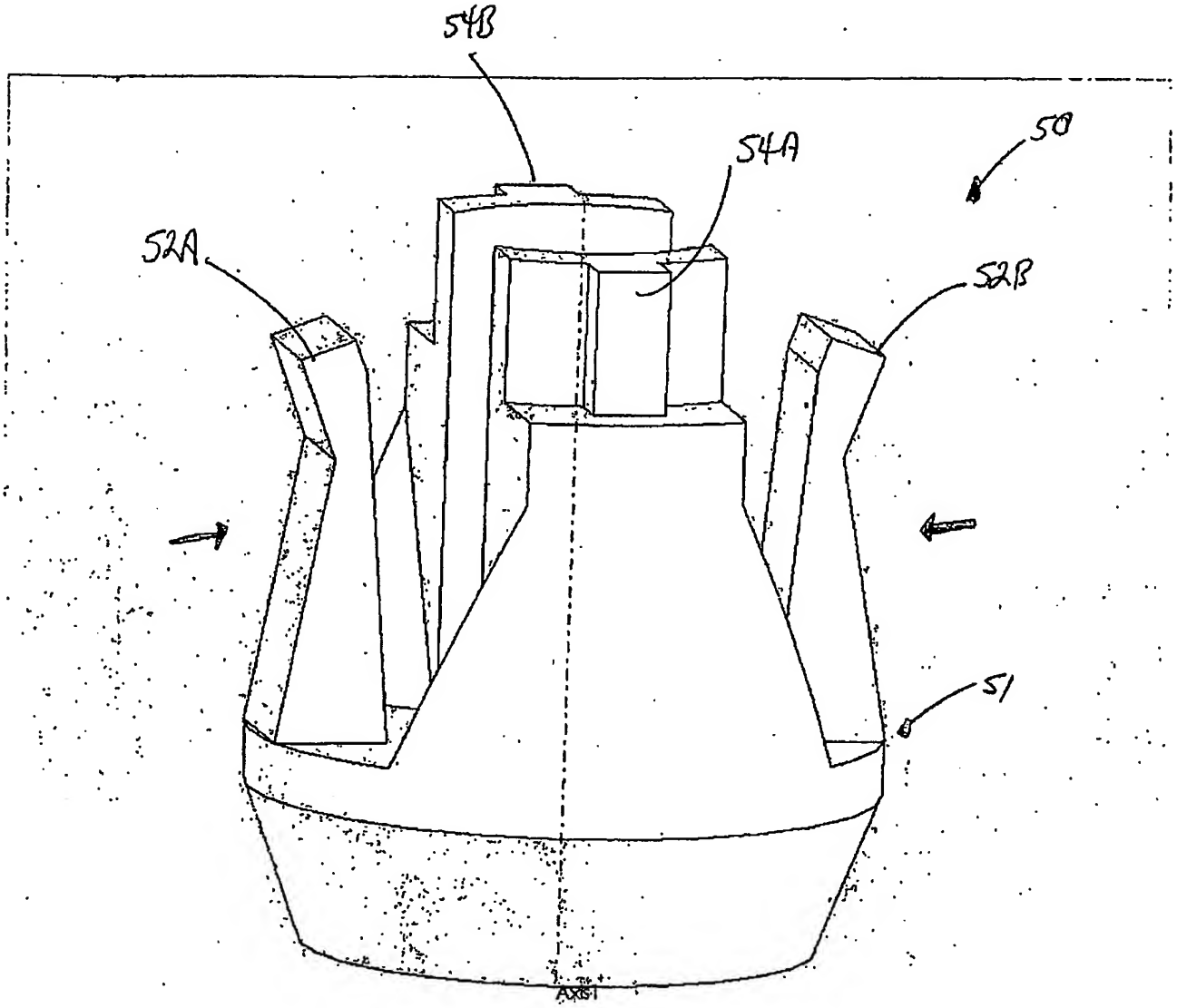
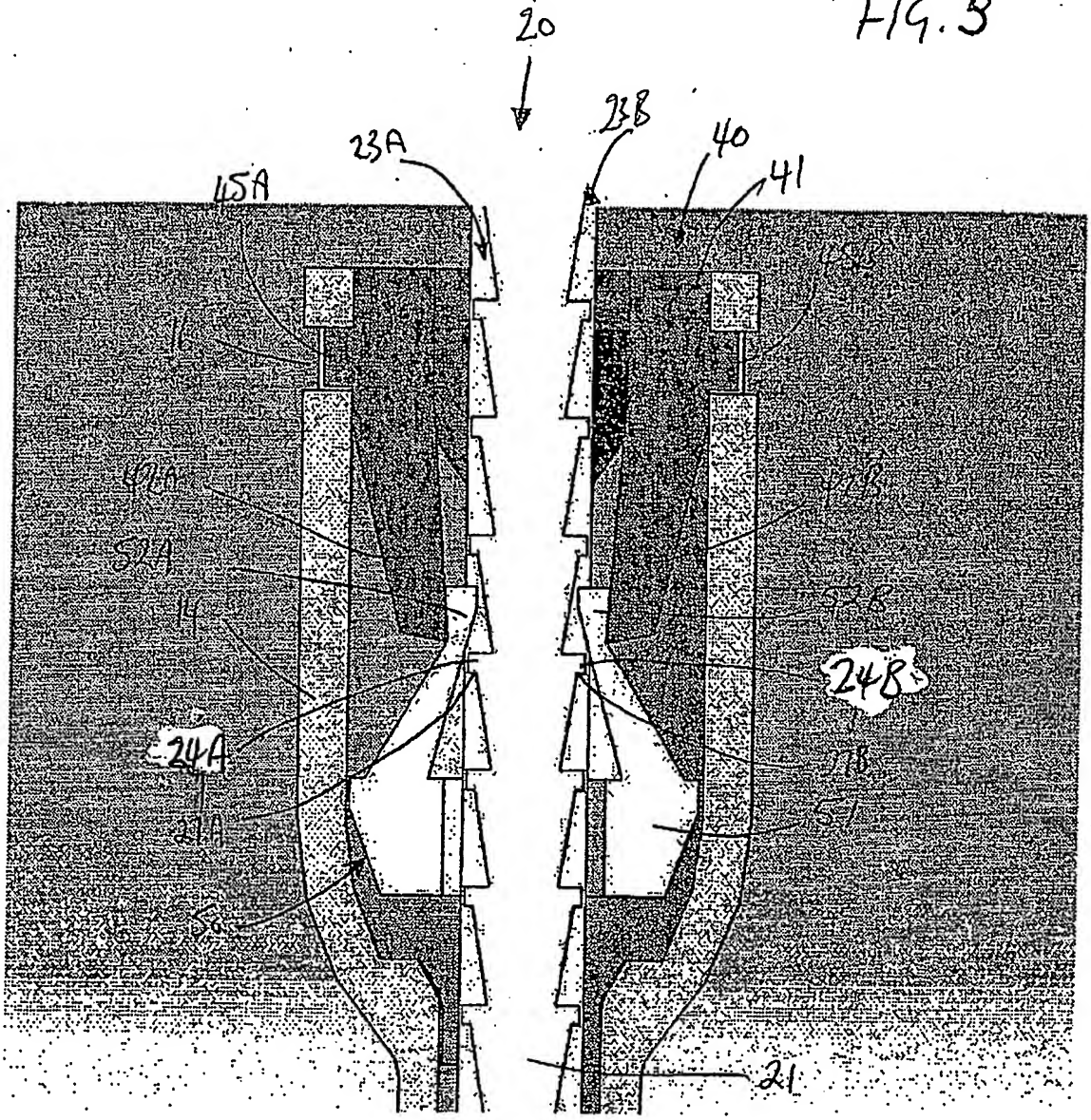


FIG. 4

FIG. 5



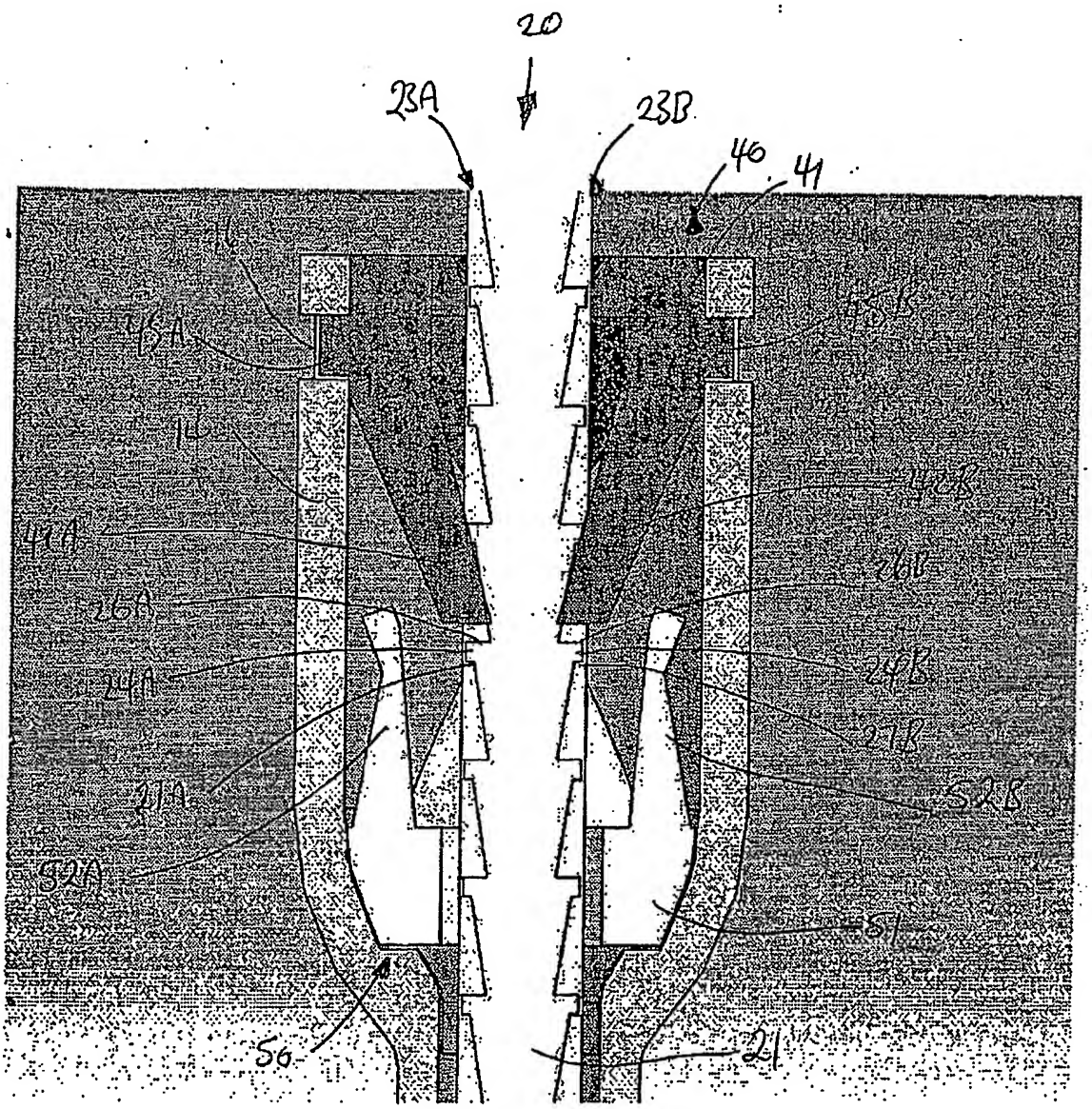

20
23A
23B
46
41
16
15A
14
47A
26A
24A
21A
52A
56
45B
47B
26B
24B
21B
52B
51
21

FIG. 6

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

FISHER ADAMS KELLY
Level 13, AMP Place
10 Eagle Street
Brisbane, Queensland 4000
AUSTRALIE

Date of mailing *(day/month/year)* 14 March 2005 (14.03.2005)	
Applicant's or agent's file reference 12846PC2-MLE	**IMPORTANT NOTIFICATION**
International application No. PCT/AU05/000106	International filing date *(day/month/year)* 28 January 2005 (28.01.2005)
International publication date *(day/month/year)*	Priority date *(day/month/year)* 28 January 2004 (28.01.2004)
Applicant UNITRACT SYRINGE PTY LTD et al	

1. By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. *(If applicable)* The **letters "NR"** appearing in the right-hand column denote **a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau** under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

3. *(If applicable)* **An asterisk (*)** appearing next to a date of receipt, in the right-hand column, denotes **a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b)** (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
28 January 2004 (28.01.2004)	2004900363	AU	15 February 2005 (15.02.2005)

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